REMARKS

The Office Action dated April 1, 2004 had been read and carefully considered and the present amendment presented to better define the subject invention.

In that Office Action, an objection was made to the claim numbering and Applicant's attorney has again renumbered the claims to make the claim numbering consistent in order to overcome that objection. Other objections as to the claim dependencies have also been corrected.

Claims 1-4 and 6 were rejected under 35 U.S.C. 102(b) as being anticipated by Held, U.S. Patent 2,541,246. Claims 1-4 and 6 were also rejected under 35 U.S.C. 102(b) as being anticipated by Agee *et al*, U.S. Patent 5,306,284. Claim 1-4 and 6-9 were further rejected under 35 U.S.C. 102(b) as being anticipated by Rhum *et al*. Claims 27-29 and 32 were rejected under Section 102(b) as being anticipated by Ogirala, U.S. Patent 5,302,684.

Next, claims 1-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ogirala in view of Alfranca, U.S. Patent 4,729,374. Claims 13, 16-23 and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rhum *et al* in view of Marini, U.S. Patent 6,077,290. Finally, claim 30 was rejected under Claims 1-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Origala.

Claims 10-12, 14, 15, 24, 25, 31 and 33 were indicated as being allowable if rewritten in independent form to include all of the limitations of their base claims and any intervening claims. Applicant appreciates the indication of allowability of those claims.

Accordingly, Applicant has amended the claims in order to better define the invention over the cited references.

Initially, in order to fully appreciate the amendments made herein, a summary of the invention may be of assistance to better explain the differences between the present invention

and the cited references.

The device of this invention is intended to obtain a tissue sample from the parietal pleura of a patient and which surface is the inside layer of the rib cage within the pleural cavity. That layer is exterior of the lungs and occupies a relatively small, narrow space between the pleural surface and the lungs themselves. As such, the device of the present invention enters the pleural cavity, the articulating members moved outwardly to their extended position and the needle is then pulled back slightly to actually encounter that pleural layer that faces the lungs. The operative surfaces of the articulating members thus are in contact with the surface where the sample is to be collected and the device itself is rotated so that a sample of the tissue is scraped or brushed from the surface to collect the sample on the operative surface of the articulating members. Once the sample has been collected, the articulating members are retracted for removal of the needle from the patient.

Accordingly, the difference is stark between the use of the present invention and the devices of the newly cited references. The newly cited references are of the type that perform a cutting operation to cut the tissue rather than gather a sample for purpose of analysis and none could be used to gather the sample from the pleural cavity. For example, Held is a curved forceps instrument that is used to sever the sphincter in draining a tumor and the blade is, therefore openable and positionable to capture the sphincter and then the blade is retracted in order to sever that sphincter. There is no suggestion that the Held device could be used to recover a sample of tissue from the pleural cavity and obvious it could not be so used.

Similarly the Agee *et al* reference discloses a surgical instrument to cut tissue and to move the blade in a restricted motion to carry out that cutting action and there is no suggestion, nor could there be, that the device could be manipulated or rotated to collect a sample of tissue from a patient, far less a sample of tissue within the pleural cavity of that patient.

The same is true of Rhum *et al* where the device for opening a hole in tissue and includes a tissue divider that is not located at or anywhere near the distal end of the device

and therefore, again, could never be used in the removal of a biopsy sample from the pleural cavity since the actuating mechanism for opening the tissue parting elements is located at the distal end of the Rhum *et al* device and that location would appear to severely affect the lungs if used in the manner of Applicant's device.

The Ogirala *et al* reference does carry out the collection of a biopsy tissue from a patient, however, as will become clear, again, the tissue is cut or ripped from the site and is one of the typical prior art references mentioned by Applicant in the specification as not providing the features of the present invention.

As such, with that background, it is clear that none of the primary references cited by the Examiner could ever be used to carry out the purposes of the present invention. It is noted, however, that the Examiner is not giving patentable weight to the preamble and to the functional language following the "whereby" statement so Applicant has further amended the language of the claims to add clarifying language that points out the physical differences in the instrument itself that allow the present invention to carry out its unique procedure of removing the sample of tissue from within the pleural cavity of a patient.

Thus, claim 1 has been amended to recite that there are a "pair of oppositely disposed peripheral openings" that are formed in the outer tube and also that there are a corresponding "two articulating members" that are movable from their retracted positions to their extended positions where those members extend outwardly therefrom. As now described in claim 1, therefore, the two articulating members are consistent with the specific use of Applicant's device, that is, scraping a tissue sample from the surface of the pleural cavity by contacting that surface and then manipulating, by rotation, the device to obtain the tissue samples.

The wording amendment to claim 1 also serves to fully distinguish the present invention over the cited references and points out more clearly the differences in the physical construction of the present invention over the devices of the references due to the totally different uses as previously discussed. Again, for example, in Held, there is only one cutting blade since, of course, there is only a need for one such blade in severing the sphincter and

there would be no need to have two blades, nor, due to the construction of Held, would there appear to be any way to modify Held to add a second blade even if one were to try.

The same is true of Agee *et al* where there is also a cutting action by the instrument and only one blade used to carry out that purpose and, to the end, there is no suggestion that more than one blade would or could ever be used with the Agee *et al* device, far less two articulating members that are moved from a retracted to an extended position in order to scrape tissue samples from the pleural cavity of the patient.

Similarly, in Rhum *et al*, while there may be more the one "tissue parting element" utilized, the clear import of the device, again is dictated by its totally different use than the biopsy needle of the present invention. In Rhum *et al*, the tissue parting elements are just that, i.e. elements that are used to cut an opening in the tissue and not scrape tissue from any internal area of the patient. As such, the Rhum *et al* device could never be used for the purpose of the present biopsy needle to obtain a sample of tissue from the pleural cavity by scraping an internal surface of a patient.

Thus, with the present invention, it is paramount that the pair of articulating members be located at the distal end of the device, as clearly recited in the claim language of claim 1, so that the articulating members can remain in the rather restricted space between the lung and the surface of the pleural cavity where the tissue samples are being taken. With the Rhum *et al* device, the operative mechanism is at the distal end and could not, therefore, even be considered for use in the pleural cavity since that operative mechanism would require displacement of a lung, possibly leading to a rupture of the lung, and thus, having the articulating members of applicant's invention located at the distal end of the biopsy needle is clearly dictated by the specific use of the present invention and one that is distinguishable over the Rhum *et al* reference by the language of claim 1.

As such, therefore it is submitted that the language of claim 1, as now amended, clearly distinguishes the present invention over the cited references used in the Section 102(b) rejection and that no secondary reference can be used to modify those references in

view of the completely different use of the devices of those references that relate to the cutting of tissue and not to the obtaining of a sample thereof. Any such modifications would seem to go against the very teaching of the primary references and their intended use.

Taking next, independent claim 13, that claim has also been amended in accordance with the prior discussion in order to add the presence of two peripheral openings and two articulating members and is submitted to be patentable over the cited references for the same reasons as discussed with respect to claim 1. In connection with the present amendment to claim 13, claim 22 has been canceled.

In the method claim, claim 27, the claim has been amended to state that the needle is rotated in order to move the articulating member across the tissue in order to obtain a sample of that tissue and points up the inventive method where the tissue is scraped from the surface of the pleural cavity. As opposed to the device claims, it is submitted that the specific use of the method in claim 27 must be given weight and that therefore the present method can be fully distinguished over the Ogirala reference by the specific method steps set forth in claim 27.

As is clear in the use of the Ogirala biopsy needle, the method is different than that disclosed and specifically claimed in the present invention and that distinction is specifically referenced in the present specification. The biopsy needle of Ogirala simply tears a sample of tissue from the target area of the patient as the needle is inserted into the patient and then pulled outwardly therefrom. Nothing in the Ogirala reference would indicate that such needle would have any effect or use if rotated to collect the sample and it would not seem to have any such effect since the method of collection of Ogirala is to pull the needle outwardly to collect the sample, thereby illustrating the totally different method of collecting the tissue sample of Ogirala as opposed to the present method.

Thus, as now claimed, the present method has the articulating member moved from its extended position and then the <u>needle itself</u> is rotated in order to move the articulating members to brush or move the operative surface of the articulating members across the

surface of the pleural cavity to collect the sample and it is submitted to be a totally different method than that described in the Ogirala reference.

Accordingly it is submitted that, as now amended, the claims of the present application are in allowable form and an allowance of the present application is respectfully solicited.

Respectfully submitted

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